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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,599	01/13/2000	Randy Kristopher Bower	CDS-0215	7220

7590 09/27/2004

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/482,599

Applicant(s)

BOWER ET AL.

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/7/10/27/2003
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 4, 2004 has been entered.
2. Claims 1-4 are objected to because of the following informalities: In claim 1, lines 2-3 and 6, "that resulting" is grammatically incorrect. Appropriate correction is required.
3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
4. Instant claim 1 now recites, "a method for detecting failures that can result from multiple failure modes in an analyzer. ...". However, the specification does not support "a method for detecting failures that can result from multiple failure modes, but rather multiple detection schemes (i.e. error detection measures), are used for the detection of the same failure mode, see page 7, lines 22-29. Furthermore, the specification states "(b)y taking advantage of the multiplying effect of multiple detection schemes targeting the same failure mode, each detection scheme does not have to be extremely robust in order to achieve a robust detection system "

5. Specifically, on page 18, applicant describes the primary example in which the "failure [mode]" is a low or non-existent chemiluminescent signal, three errors (reagent, signal reagent and dilution systems) are identified and their possible sources are determined, and then one detection measure for each error (RAVE, DIVE, SAIL) is provided, resulting in multiple error detection measures (three) for the **single failure mode** of low or non-existent chemiluminescent signal.
6. Note that applicant has been inconsistent in the use of terms in the specification and claims, resulting in a lack of clarity and inadequate written description. That is, applicant has used the term "failure" indiscriminately throughout the specification, rather than limiting use of this term to the failure modes claimed, making the meaning of the claims in view of the specification unclear.
7. Further, claim 3 is not described in that at least providing an analyzer, identifying error detection measures and implementing error detection measures require human intervention.
8. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The inconsistent use of terms related to "errors" and "failures" as explained throughout this action.

9. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. In claim 1, part f, it is unclear if "an assay failure" is the same or different from the assay failures of part b. In claim 1, it is unclear if the "failures" in the preamble are the same as the "failure modes," "assay failures," "potential errors" or some other failures. In claim 1, part f, it is unclear what is intended by "reducing errors"—errors in what? Or does applicant intend the previously recited "potential errors"? See also claim 1, part d, with respect to "clinically significant error". With so many similar terms, the claim language must be rigorous in usage and antecedent basis, as well as consistent with the specification.
11. In claims 3 and 4, it is unclear what portions of claim 1 are performed using the claimed methods.
12. Applicant's arguments filed July 7, 2004 have been fully considered but they are not persuasive.
13. With respect to the rejection under 35 USC 112, first paragraph, applicant's analysis of the disclosure is inconsistent with the claim language. Applicant has improperly interchanged the terms "failure," "failure mode," "assay failure," "error," and "sources of error", which the claim sets forth as different things. For example, on page 6, lines 8-9 of the response filed July 7, 2004, applicant equates the terms "potential sources of failure" and "failure modes" and equates "failure" and "error." On page 6, line 10 of the same response, applicant has equated "failure mode" and "potential sources

of error". The terms used in the claims are "failure mode," "assay failure," "potential error," and "potential sources of error". Until and unless applicant is able to keep these terms distinct and equate these terms with steps in the specification, applicant's arguments will remain irrelevant to the claim language. An analysis of the specification using the correct terms has been made by the examiner above, and a comparison of the examiner's and applicant's analysis is given below. Applicant's erroneous analysis of his own disclosure demonstrates how inadequate the written description is, and how unclear the claims are.

<u>Claim language</u>	<u>Examiner example</u>	<u>Applicant example</u>
Failure mode	low/no chemiluminescent signal	occluded probe
Potential error	reagent management	reagent management
Potential source of error	occluded probe	occluded probe

Further, the examiner notes that the specification defines "assay failure" at page 2, lines 18-20:

An assay failure, as the term is used in this specification, occurs when an assay result is obtained that is believable yet unacceptably inaccurate and if used as the sole source of clinical data would result in an improper clinical choice (i.e., treatment).

The rejection over Farmer is withdrawn in that it does not relate to an analyzer for conducting clinical assays or errors resulting in assay failures as those terms are interpreted in view of the instant disclosure.

14. Note that the EP Search Reports have been considered, but the claims corresponding to the instant claims were not searched by the EP. Note that the Search Reports have been lined through because the Search Reports provided are not published documents.

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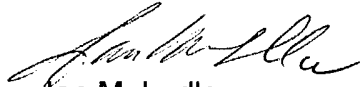
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

EP 0753750 A2 teaches an analyzer and method having a failure mode (unusual test result, col. 1, lines 50-55), error (fluid moving system, col. 1, lines 43-44), sources of error (col. 2, lines 15-20), and multiple error detection measures (col. 2, lines 37-42), but fails to teach or suggest the steps of determining the probability of an error source resulting in a clinically significant error or selecting and implementing the multiple error detection measures based on the claimed criteria.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
September 22, 2004